DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Zelnorm
Docket No.: 03E-0416

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 5,510,353, filed by Novartis Pharmaceuticals under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Zelnorm, the human drug product claimed by the patent.

The total length of the regulatory review period for Zelnorm is 2,826 days. Of this time, 1,931 days occurred during the testing phase and 895 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: October 30, 1994.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 30, 1994.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: February 11, 2000.

   FDA has verified the applicant's claim that the new drug application (NDA) for Zelnorm (NDA 21-200) was initially submitted on February 11, 2000.

3. The date the application was approved: July 24, 2002.

   FDA has verified the applicant's claim that NDA 21-200 was approved on July 24, 2002.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Thomas Hoxie
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